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D E C I S I O N
of 13 July 2006

Case Number: T 0137/04 - 3.3.02

Application Number: 98929228.9

Publication Number: 1011673

IPC: A61K 31/445

Language of the proceedings: EN

Title of invention:
Novel NIDDM regimen

Patentee:
NOVO NORDISK A/S

Opponents:
Novartis AG
Ajinomoto Co., Inc.
Merck Patent GmbH

Headword:
NIDDM co-administration regimen/NOVO NORDISK

Relevant legal provisions:
EPC Art. 100(c), 123(2)

Keyword:
"The subject-matter of all sets of claims contravenes the requirements of Article 123(2) EPC"

Decisions cited:
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Catchword:
-

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Case Number: T 0137/04 - 3.3.02

D E C I S I O N
of the Technical Board of Appeal 3.3.02
of 13 July 2006

Appellant: (Patent Proprietor)
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Decision under appeal:
Decision of the Opposition Division of the European Patent Office posted 27 November 2003 revoking European patent No. 1011673 pursuant to Article 102(1) EPC.

Composition of the Board:

Chairman: U. Oswald
Members: M. C. Ortega Plaza
P. Mühlens

Summary of Facts and Submissions

I. European patent No 1 011 673, based on European application No 98 929 228.9, which was filed as international application WO 98/56378, was granted on the basis of one single claim.

Claim 1 as granted read as follows:

"1. Use of repaglinide or N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament to be used in combination with metformin in the treatment of type 2 diabetes."

II. Opposition was filed and revocation of the patent in its entirety was requested pursuant to Article 100(a) EPC and pursuant to Article 100(c) EPC because the patent extended beyond the content of the application as filed.

III. The appeal lies from the decision of the opposition division revoking the patent in suit (Articles 102(1), (3) EPC) on the basis of the sets of claims filed during the oral proceedings before the opposition division as main request and first auxiliary request.

According to the opposition division's findings both requests contravened the requirements of Article 123(2) EPC because the specific use "for the treatment of postprandrial hyperglycaemia in type 2 diabetes" introduced in claim 1 of both requests for characterising the therapeutic use of the combination of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine (nateglinide) with metformin was

disclosed in the application as filed only in the context of monotherapy with short-acting hypoglycaemic agents such as nateglinide.

IV. The patent proprietor (appellant) lodged an appeal against said decision and filed grounds of appeal. The appellant filed with its grounds of appeal a main request and 29 auxiliary requests.

V. The respondents (opponents 1 to 3) filed counterarguments thereto.

VI. A board's communication dated 9 February 2006 conveyed the board's preliminary opinion in respect of the lack of admissibility of those auxiliary requests containing new dependent claims which left unimpaired the scope of the independent claim to which they referred. The board also informed the parties that the framework of the oral proceedings concerned Articles 123 and 84 EPC.

VII. The appellant filed with its letter of 5 June 2006 a main request and auxiliary requests 1 to 29.

The main request and auxiliary requests 1-3, 12-14 filed with the letter of 5 June 2006 corresponded identically to the main request and auxiliary requests 1-3, 12-14 filed with the grounds of appeal. The auxiliary requests 4-11 and 15-29 filed with the letter of 5 June 2006 corresponded to those sets of claims of the auxiliary requests of the same numbering filed with the grounds of appeal with the dependent claims deleted.

Claim 1 of the main request read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament to be used in combination with metformin in the treatment of postprandial hyperglycaemia in type 2 diabetes."

Claim 1 of auxiliary request 1 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament for the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein the medicament is to be used in combination with metformin."

Claim 1 of auxiliary request 2 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate meal-related insulin secretion to be used in combination with metformin in the treatment of postprandial hyperglycaemia in type 2 diabetes."

Claim 1 of auxiliary request 3 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate meal-related insulin secretion for the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein the medicament is to be used in combination with metformin."

Claim 1 of auxiliary request 4 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament to be used in combination with metformin in the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals."

Claim 1 of auxiliary request 5 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament for the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein the medicament is to be used in combination with metformin, and wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals."

Claim 1 of auxiliary request 6 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to simulate meal-related insulin secretion to be used in combination with metformin in the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals."

Claim 1 of auxiliary request 7 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate meal-related insulin secretion for the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein the medicament is to be used in combination with metformin, and wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals."

Claim 1 of auxiliary request 8 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament to be used in combination with metformin in the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished."

Claim 1 of auxiliary request 9 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament for the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein the medicament is to be used in *combination with metformin, and wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished*." (as stated by the appellant during the oral proceedings before the board, the text in

italics was crossed by mistake in the version filed with the letter of 5 June 2006)

Claim 1 of auxiliary request 10 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate meal-related insulin secretion to be used in combination with metformin in the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished."

Claim 1 of auxiliary request 11 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate meal-related insulin secretion for the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein the medicament is to be used in combination with metformin, and wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished."

Claim 1 of auxiliary request 12 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament to be used in combination with metformin in the treatment of type 2 diabetes."

Claim 1 of auxiliary request 13 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament for the treatment of type 2 diabetes, wherein the medicament is to be used in combination with metformin."

Claim 1 of auxiliary request 14 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate meal-related insulin secretion to be used in combination with metformin in the treatment of type 2 diabetes."

Claim 1 of auxiliary request 15 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate meal-related insulin secretion for the treatment of type 2 diabetes, wherein the medicament is to be used in combination with metformin."

Claim 1 of auxiliary request 16 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament to be used in combination with metformin in the treatment of type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals."

Claim 1 of auxiliary request 17 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament for the treatment of type 2 diabetes, wherein the medicament is to be used in combination with metformin, and wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals."

Claim 1 of auxiliary request 18 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate meal-related insulin secretion to be used in combination with metformin in the treatment of type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals."

Claim 1 of auxiliary request 19 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate meal-related insulin secretion for the treatment of type 2 diabetes, wherein the medicament is to be used in combination with metformin, and wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals."

Claim 1 of auxiliary request 20 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament to be used in combination with metformin in the treatment of type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished."

Claim 1 of auxiliary request 21 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament for the treatment of type 2 diabetes, wherein the medicament is to be used in combination with metformin, and wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished."

Claim 1 of auxiliary request 22 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate meal-related insulin secretion to be used in combination with metformin in the treatment of type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished."

Claim 1 of auxiliary request 23 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament adapted to stimulate insulin secretion for the treatment of type 2 diabetes, wherein the medicament is to be used in combination with metformin, and wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished."

Claim 1 of auxiliary request 24 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament for the treatment of type 2 diabetes, for administration in relation to meals for the stimulation of insulin secretion in connection with a meal, in combination with treatment with metformin."

Claim 1 of auxiliary request 25 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine for the manufacture of a medicament for the treatment of type 2 diabetes, for administration in relation to meals for the stimulation of insulin secretion in connection with a meal, in combination with treatment with metformin, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished."

Claim 1 of auxiliary request 26 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine in combination with metformin for the manufacture of a medicament of postprandial hyperglycaemia in type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals."

Claim 1 of auxiliary request 27 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine in combination with metformin for the manufacture of a medicament for the treatment of postprandial hyperglycaemia in type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished."

Claim 1 of auxiliary request 28 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine in combination with metformin for the manufacture of a medicament for the treatment of type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine is to be administered in relation to meals."

Claim 1 of auxiliary request 29 read as follows:

"1. Use of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine in combination with metformin for the manufacture of a medicament for the treatment of type 2 diabetes, wherein N-((trans-4-isopropylcyclohexyl)-

carbonyl)-D-phenylalanine is to be administered in relation to meals at a time from 10 minutes before the meal starts to 10 minutes after the meal is finished."

VIII. Oral proceedings took place on 13 July 2006.

IX. Having regard to the fact that claim 1 of all the requests concerns the use of the combination nateglinide and metformin in a co-administration regimen, the board requested the appellant to submit its arguments in respect of the requirements of Article 123(2) EPC for this specific combination, appearing in all requests.

The appellant's arguments may be summarised as follows:

The requirements of Article 123(2) EPC should not be construed too restrictively. The application as filed should be taken as a whole. It should be therefore investigated what information was derivable by the skilled person when taken the specification as a whole. The combination therapy of nateglinide and metformin did not result from an unallowable selection from two lists since nateglinide was specified as the short-acting hypoglycaemic agent to be used in a single claim, either claim 3 or claim 8 as originally filed, worded as dependent claim 1 or 6, respectively. Moreover, claims 5 and 10, which were dependent on claims 1 to 4 or on claims 6 to 9 respectively, specified a co-administration regimen with a long-acting hypoglycaemic agent. The long-acting hypoglycaemic agent was defined in claim 12, dependent on claim 10, as to be chosen from a list of eight options, where metformin appeared as the first option. Therefore, there the combination

nateglinide, metformin merely concerned the selection of one single option from one single list by deletion of the other options of the list.

As regards the use defined in originally filed claims 1 to 4, their counterpart could be found on page 2 of the description as filed. Moreover, the definition for the long-acting hypoglycaemic agent of claim 5 was to be found on page 7, lines 8-10, where metformin appeared as the first listed option.

Although it was a fact that there was no literal basis in the description as originally filed for the specific combination nateglinide, metformin, the combination was directly and unambiguously derivable for the skilled person when reading the whole application as filed. Moreover, it did not relate to the selection from two lists.

The fact that some aspects disclosed in the application as originally filed were no longer claimed in the sets of claims on file was irrelevant for the considerations in relation to added subject-matter. The whole description concerned clearly related features of the invention.

X. The respondents' arguments may be summarised as follows:

The appellant had not been able to point out any disclosure in the application as originally filed where the specific combination nateglinide, metformin was disclosed. The only specific combination disclosed in the application as originally filed was repaglinide and metformin. However, this combination was no longer

claimed. The disclosure on page 2 of the application as originally filed only related to the use of a short-acting hypoglycaemic agent. Nateglinide was only one among three possibilities. Moreover, claim 5 refers to a long-acting hypoglycaemic agent only generically. As regards claim 12 metformin is only one long-acting hypoglycaemic agent among eight possible. Although claim 12 refers to claim 10, there is no direct pointer to nateglinide. Hence, there is no unambiguous and direct disclosure of the combination nateglinide, metformin. As regards the disclosure on page 7, lines 8 to 10, it did not concern an exhaustive definition of the long-acting hypoglycaemic agents but merely referred to a list of examples including several compound classes and several specific compounds, metformin was only one among them.

Therefore, there was no individual passage in the application as originally filed pointing to the specific combination nateglinide, metformin. Moreover, this combination was not directly and unambiguously derivable from the application as originally filed.

Moreover, the application as originally filed could not be taken as a whole without taking into consideration that the original disclosure related to separated aspects of different therapies which could not be combined without contravention of Article 123(2) EPC. Hence, specific individual embodiments could not be picked up and then be claimed as combined features in the absence of any suggestion to combine them in the application as originally filed.

The disclosure about the combination of a short-acting hypoglycaemic agent and a long-acting hypoglycaemic agent disclosed in the application as originally filed related to the respective agents as generic category but gave no information how to select them or combine them specifically.

XI. The appellant (patentee) requested that the decision under appeal be set aside and that the patent be maintained on the basis of the main request or on the basis of one of the auxiliary requests 1 to 29, all filed with the letter dated 5 June 2006.

The respondents (opponents) requested that the appeal be dismissed.

Reasons for the Decision

1. The appeal is admissible.

2. The compound N-((trans-4-isopropylcyclohexyl)carbonyl)-D-phenylalanine, appearing in the claims, is nateglinide.

NIDDM means non-insulin dependent diabetes mellitus.

The citations referring to the application as originally filed relate to the international application WO 98/56378.

3. As expressed by the board at the beginning of the oral proceedings claim 1 of all requests concerns the use of the combination nateglinide and metformin in a

co-administration regimen, these findings have not been disputed by the parties.

3.1 Therefore, in order to assess whether the requirements of Article 123(2) EPC have been met by the sets of claims on file, it has to be investigated whether the application as filed disclosed in an individualised form such specific combination.

Claim 1 as originally filed read as follows:

"1. Use of **a short-acting hypoglycaemic agent** capable of stimulating insulin secretion from ß-cells for the manufacture of a medicament adapted to stimulate meal-related insulin secretion **for the treatment of postprandial hyperglycaemia in NIDDM patients**." (emphasis added)

Claim 2, 3 and 4 as originally filed relate each to the use of a specific short-acting hypoglycaemic agent.

Claim 3 as originally filed read as follows:

"3. Use according to claim 1 of N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine."

Claim 5 as originally filed read as follows:

"5. Use according to any one of claims 1 to 4 for the manufacture of a **medicament which further comprises a long-acting hypoglycaemic agent**." (emphasis added)

As it becomes evident from the reading of claims 1, 3 and 5 as originally filed there is neither disclosure

nor indication to the specific combination nateglinide, metformin. The passages on page 2 of the description, lines 17-33 are the counterpart to claims 1 to 4 and relate to the disclosure concerning the use of a short-acting hypoglycaemic agent for the treatment of postprandial hyperglycaemia in NIDDM. As short-acting hypoglycaemic agent three preferred options are disclosed, namely repaglinide, nateglinide and gliquidone.

However, there is no disclosure on page 2 either of a combination therapy or of a co-administration regimen with a long-acting hypoglycaemic agent.

Leaving aside the fact that it is not immediately apparent whether or not the passage on page 7, lines 8-10, which discloses examples of long-acting hypoglycaemic agents, is directly applicable to the features of all claims, the contents of the said passage have to be considered within their context. It can be read on page 7, lines 5 and 6, and 8 to 10:

"Repaglinide is a short-acting hypoglycaemic agent with a short half-life. Examples of other short-acting hypoglycaemic agents with a short half-lives are gliquidone and A-4166." (A-4166 is nateglinide)

"Examples of long-acting hypoglycaemic agents are biguanides such as metformin, and sulfphonylureas such as chlorpropamide, tolbutamide, glibenclamide, glibornuride, gliclazide and glipizide. A further example of a long-acting hypoglycaemic agent is troglitazone."

There is neither explicit nor implicit disclosure on page 7 of the description in respect of the specific combination therapy nateglinide, metformin. Furthermore, there is no hint on page 7 regarding the choice of any specific short-acting hypoglycaemic agent as most preferred and the same applies to the choice of a specific long-acting hypoglycaemic agent.

Furthermore, claim 6 as originally filed read as follows:

"6. A method of **treating NIDDM** which comprises **stimulating the insulin-secretion in connection with a meal** by administering to a patient in need of such a treatment, in relation to the meals, an effective amount of a **short-acting hypoglycaemic agent**." (emphasis added)

Claims 7 to 9 as originally filed read as follows:

"7. A method according to claim 6 wherein the short-acting hypoglycaemic agent is repaglinide."

"8. A method according to claim 6 wherein the short-acting hypoglycaemic agent is N-((trans-4-isopropylcyclohexyl)-carbonyl)-D-phenylalanine."

"9. A method according to claim 6 wherein the short-acting hypoglycaemic agent is gliquidone."

Claim 10 as originally filed read as follows:

"10. A method according to any of the claims 6 to 9 **wherein the regimen**, *further to the meal-related administration of a short-acting hypoglycaemic agent*, **comprises treatment with a long-acting hypoglycaemic agent**." (emphasis added)

Therefore, claim 10 since it refers (as multiple reference) to any of the claims 6 to 9 covers the co-administration regimen of a short-acting hypoglycaemic agent and a long-acting hypoglycaemic agent in generic terms, where either both agents are generically defined (reference to claim 6) or where the short-acting hypoglycaemic agent is to be chosen among the three possible options (reflected by the multiple-reference to any of claims 7 to 9).

Claim 12 as originally filed read as follows:

"12. A method according to claim 10 or 11 wherein the **long-acting hypoglycaemic agent is selected from** the group comprising metformin, chlorpropamide, tolbutamide, glibenclamide, glibornuride, gliclazide, glipizide and troglitazone." (emphasis added)

Hence, claim 12 defines the long-acting hypoglycaemic agent for the co-administration regimen defined in claim 10 as to be selected from a list of eight possible options. Therefore, since claim 10 contains a multiple reference "according to any of the claims 6 to 9", claim 12 covers the generic combination of one among eight long-acting hypoglycaemic agents with either a generically defined short-acting hypoglycaemic

agent (claim 6) or with one specific short-acting hypoglycaemic agent to be chosen from any of the claims 7 to 9. This amounts to a double selection, i.e. the two selections from two pools of options (one within eight possible compounds and the other within three specific options).

Further inspection of the description as originally filed shows that the only specific combination of a short-acting hypoglycaemic agent and a long-acting hypoglycaemic agent disclosed relates to repaglinide and metformin. However, this combination is no longer claimed in the sets of claims on file.

Therefore, there is no individualised combination nateglinide, metformin pointed out either by the wording of the originally filed claims or by the description when taken as a whole.

3.2 Finally, the co-administration regimen is the essence of the claimed invention and the now specifically claimed co-administration regimen, where the two components have been selected, may have been encompassed by the generic disclosure of the application as originally filed but was not singled out in such individualised form in the original disclosure.

3.3 Consequently, claim 1 of all sets of claims contravenes the requirements of Article 123(2) EPC.

Order

For these reasons it is decided that:

The appeal is dismissed.

The Registrar: The Chairman:

A. Townend U. Oswald